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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/068,804	05/14/1998	SAMUEL I. MILLER	00786/292002	2704

7590

05/13/2002

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EXAMINER

BASKAR, PADMAVATHI

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 05/13/2002

25

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/068,804

Applicant(s)

MILLER, SAMUEL I.

Examiner

Padmavathi v Baskar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17, 18 and 46-95 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17, 18 and 46-95 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 September 1998 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

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DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/26/02 has been entered.
2. Applicant's amendment filed on 2/26/02 (paper # 24) is acknowledged. Claims 46-50, 52-56, 58-62, 64-68, 70-74, 76-80 and 82-85 have been amended. New claims 87-95 have been added. Claims 17-18 and 46-95 are pending in the application.
3. In view of amendment to the claims, the Examiner has withdrawn 35 U.S.C. 112, first paragraph written description rejection.
4. In view of amendment to the claims, the Examiner has withdrawn the rejection of claims 46-86 under 35 U.S.C. 102 (a) as anticipated by WO 95/02048.
5. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.
7. Claims 17-18 and 46-95 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 46-95 and the dependent claims 17-18 are rejected as being vague for the recitation of "substantially". The expression "substantially" used in the claims renders the claims vague and unclear with respect to the scope of the matter for which protection is sought. Applicant states that the specification, page 10, line 1-11 defines the term "substantially pure". Examiner has reviewed the specification and understands that substantially pure DNA refers to an isolated and purified DNA. Applicant is advised to amend the claims to recite "an isolated and purified DNA" since the metes and bounds of the term "substantially" are not clear.

Claims 88, 89 and 91 are rejected as being vague and unclear for the recitation of "can induce bacterial mediated endocytosis in the absence of a wild type SspC, SspD and SspA polypeptide". It is unclear to the examiner how a polypeptide encoded by substantially purified nucleic acid molecule can induce bacterial mediated endocytosis since endocytosis is mediated by bacteria.

Claim Rejections - 35 USC § 102

8. The rejection of claims 17-18, 46-86 and newly added claims 87-95 under 35 U.S.C. 102 (a) as anticipated by Hermant et al 1995 (Mol. Biol 17:781-789) is maintained as set forth in the previous office action.

Applicant's submission of evidence "Exhibit D" is not sufficient to overcome the rejection because the reference was made available to the public (October 3, 1995) before the filing date of the priority application (November 14, 1995). The submitted evidence "Exhibit C" declaration contains conclusionary statements without sufficient evidentiary support. Therefore, the declaration is insufficient to obviate the rejection. Evidentiary support may include copies of pertinent lab notebook entries and submission of the sequences claimed to any established data bases prior to the prior art dates by the inventor.

Applicant argues that the supporting evidence was in the form of contemporaneous documents that are pertinent lab notebook entries, the examiner is not free to simply dismiss this evidence and it is unclear to the applicant what more the Examiner requires. It is the

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Examiner's position that the Office did not simply dismiss the evidence provided by the applicant and the Examiner does not need (i.e., want) more than the required evidentiary support in order to overcome the cited prior art. The Declaration provided by Dr.S.Miller is not sufficient because (1) the copy of the Declaration (sent by Fax On 2/14/01) is not clear and some of the sentences could not be read as the quality of the print out is poor (2) the Declaration indicates that the sequencing of the open reading frames were produced prior to July 8, 1995 and additional sequencing of the same clone was produced again which lead to the sequences of SspB, SspC, SspD and SspA. However, the sequences submitted do not indicate which of the two sequences applicant has provided. Further, the sequences submitted in the form of contemporaneous documents that are pertinent lab notebook entries do not indicate the information about clone pVV8-1 and the sequences obtained from it are the same as the claimed sequences. Applicant provided a simple print out of the sequences without any information to support that these sequences have been submitted to any established database prior to the cited prior art publication date. Thus, the Declaration and the print out of sequences do not provide sufficient evidence to indicate that the conception of the claimed invention followed by diligence through an actual reduction to practice prior to the publication date of Hermant et al. Therefore, applicant's attention is directed to MPEP715 and particularly 715.07. The Office requires sufficient evidence to remove the publication as a reference under 102 (a).

9. Rejection of claims 17-18, 46-86 and newly added claims 87-95 under 35 U.S.C. 102 (a) as anticipated by Kaniga et al 1995 (J. Bact 177:3965-3971) is maintained as set forth in the previous office action.

Applicant's submission of evidence "Exhibit C " is not sufficient to over come the rejection because the reference was made available to the public (July 8, 1995) before the filing date of the priority application (November 14, 1995). The submitted evidence "Exhibit A" declaration contains conclusionary statements without sufficient evidentiary support. Therefore,

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the declaration is insufficient to obviate the rejection. Evidentiary support may include copies of pertinent lab notebook entries and submission of the sequences claimed to any established data bases prior to the prior art dates by the inventor himself.

Again Applicant asserts that the supporting evidence was from the lab notebook entries. The Declaration provided by Dr.S.Miller is not sufficient because (1) the copy of the Declaration (sent by Fax On 2/14/01) is not clear and some of the sentences could not be read as the quality of the print out is poor (2) the Declaration indicates that the sequencing of the open reading frames were produced prior to July 8, 1995 and additional sequencing of the same clone was produced again which lead to the sequences of SspB, SspC, SspD and SspA. However, the sequences submitted do not indicate which of the two sequences applicant has provided. Further, the sequences submitted in the form of contemporaneous documents that are pertinent lab notebook entries do not indicate the information about clone pVV8-1 and the sequences obtained from it are the same as the claimed sequences. Applicant provided a simple print out of the sequences without any information to support that these sequences have been submitted to any established database prior to the cited prior art publication date. Thus, the Declaration and the print out of sequences do not provide sufficient evidence to indicate that the conception of the claimed invention followed by diligence through an actual reduction to practice prior to the publication date of Hermant et al. Therefore, applicant's attention is directed to MPEP715 and particularly 715.07. The Office requires sufficient evidence to remove the publication as a reference under 102 (a).

Status of Claims

10. No claims are allowed.
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D.

4/30/02




LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
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